

## **REMARKS**

The Office Action mailed April 9, 2010 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 1, 2, 6-11, 14, 15, 17, and 19-25 are pending in this application. Claims 3-5, 12, 13, 16, and 18, indicated as withdrawn from consideration, are no longer pending in the case, having been previously canceled.

### **Interview Summary**

On the Office Action Summary page of the April 9, 2010 Office Action both boxes "2a" ("This action is FINAL") and "2b" ("This action is non-final") are checked. Applicants would like to thank the Examiner for clarifying that the Office Action is not Final in a brief telephonic interview conducted July 8, 2010 between Examiner Treyger and Patent Attorney Lester J. Anderson, Reg. No.: 45,833.

### **Claim Rejections - 35 U.S.C. § 103**

Claims 1, 2, 6-11, 14, 15, 17, and 19-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 4,029,095 to Pena et al. (hereinafter, "Pena") in view of USPN 3,783,870 to Schachet (hereinafter, "Schachet"). Applicants respectfully traverse this rejection.

Claim 1 recites, *inter alia*, "[a] manually operable pump for removing fluids from a body cavity of a subject, said pump comprising . . . an inflow connector attached to said first end, said inflow connector being adaptable for connection to an inflow conduit, the inflow conduit comprising a pleural evacuation tube for removing fluid from a plural space."

Claim 17 recites, *inter alia*, "[a] manually operable pump for removing fluids from a body cavity of a subject, comprising . . . an inflow conduit coupled to the first one-way valve and comprising a pleural evacuation tube for removing fluid from a plural space."

Claim 19 recites, *inter alia*, "[a] system for removing fluids from a body cavity, comprising . . . a manually operable pump in fluid communication with both the body cavity and the

fluid receptacle via an inflow conduit comprising a pleural evacuation tube for removing fluid from a plural space in the body cavity.”

Claim 24 recites, *inter alia*, “[a] method of removing fluid from a plural space of a body cavity of a subject, comprising: attaching a manually operable pump to a proximal end of an implanted catheter, the manually operable pump in fluid communication with a fluid receptacle via an inflow conduit comprising a pleural evacuation tube for removing fluid from the plural space.”

Applicants initially note that the Office Action alleges that Pena discloses “a manually operable pump means including elastic bulb 12a (Fig. 1) adapted to be manually compressed.” (Office Action, p. 3.) FIG. 1 does not appear to include a reference character “12a.” Reference character 10a in FIG. 1 is an elastic wall portion that is “situated so as to prevent . . . excessive pressure.” (Pena, col. 4:39-41.) The elastic wall portion 10a is not a pump. FIG. 1 uses a “small pump driven by an electric micromotor,” not a manually operable pump. (Pena, col. 2:51-52.) The Office Action may have intended to cite to “pump means 11” of FIG. 2. (Pena, col. 4:43-44, FIG. 2.)

With respect to the combination of Pena/Schachet, Applicants assert that the Office Action fails to make a *prima facie* showing of obviousness. To make a *prima facie* showing of obviousness, the Examiner should “identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-419 (2007).) A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. (See *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (warning against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “guard against slipping into the use of hindsight”); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).) Where no such explanation is given, improper use of hindsight can be inferred.

The Office Action admits that Pena does not disclose an “apparatus comprising a pleural evacuation tube for removing fluid from a plural space,” but alleges that Pena “discloses cannula 2 comprising a flange 4 being adapted for positioning into the nasal fossea (*sic*). As such, Pena motivates those of skill in the art to attach any type of tubing being adapted for positioning into the (*sic*) any particular body cavity.” (Office Action, p. 5.) Applicants respectfully disagree.

The Office Action appears to allege that, because Pena relates to positioning a flange 4 in a nasal fossae that it is obvious to add an additional device (drainage device of Schachet) and position that additional device in “any particular body cavity.”

Pena relates to a device for circulating treating fluid through the nasal fossae. Throughout the specification, Pena states that it is used for cleaning the nasal fossae. This is discussed at, for example, col. 2:49-50 and col. 3:6-8 of Pena and in the discussion of FIG. 3 beginning at col. 3:60. This is also illustrated in FIG. 3 of Pena, which illustrates how the device is used to circulate cleaning fluid using “fluid tight communication with the nasal fossae.” (Pena, col. 3:64-65.) Applicants have reviewed Pena and have not located a single teaching or suggestion that the device of Pena might be used with respect to another portion of the body, let alone that it be connected to another device that may be used in another portion of the body. On the contrary, as the Office Action admits, the flange 4 of Pena is “adapted for positioning in the nasal fossea (*sic*),” not for connection to another device. (Office Action, p. 5.) Pena connects directly to the body, not another device. As such, Pena also teaches away from the combination with Schachet because the operation of Pena involves direct connection to the body, not other devices.

According to MPEP § 2145, “[it] is improper to combine references where the references teach away from their combination.” (MPEP § 2145, p. 2100-167, Eighth Edition, Rev. 6, Sept. 2007.) Further, in MPEP § 2143.01, “[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” (MPEP § 2143.01, p. 2100-141, Eighth Edition, Rev. 6, Sept. 2007.) As discussed by the Supreme Court in *KSR Int’l Co. v. Teleflex, Inc.*, “when the prior art teaches away from combining certain known elements,

discovery of a successful means of combining them is more likely to be nonobvious.” (550 U.S. 398 (2007), 82 USPQ2d 1385, 1395 (2007), quoting *United States v. Adams*, 383 U.S. 39, 40, 148 USPQ 479 (1966).) Finally, “a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” (MPEP § 2141.02, p. 2100-126, Eighth Edition, Rev. 6, Sept. 2007.)

Accordingly, the Office Action fails to make a *prima facie* showing of obviousness and for at least this reason, independent claims 1, 17, 19, and 24 are patentable over Pena. Claims 2, 6-11, 14, 15, 20-23, and 25 are patentable because they depend from a patentable independent claim, and also because they recite features not shown or described by the cited art. Therefore, Applicants request favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

### Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicants of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection

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with the filing of this document to Deposit Account No. 50-2191 referencing docket no. 101672.0071P from which the undersigned is authorized to draw.

Dated: July 9, 2010

Respectfully submitted,

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